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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,626	01/10/2005	Manuel Rosa-Calatrava	017753-200	9366

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EXAMINER

POPA, ILEANA

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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07/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,626

Applicant(s)

ROSA-CALATRAVA ET AL.

Examiner

Ileana Popa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-43 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 7-15, 17, 18, 28, 35-39, 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 16, 19-34, 40 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the invention of Group III, drawn to an adenoviral particle comprising a trimeric modified adenoviral fiber and of the species of genetically coupled and fiber, in the reply filed on 04/13/2007 is acknowledged. The traversal is on the ground(s) that, as presently amended, the claims are drawn to a modified adenoviral fiber comprising at least one mutation located in a specific position (i.e., positions 506, 508, and/or 555 of the wild type Ad5 fiber protein set forth by SEQ ID NO: 1), which are not taught by Wickham (U.S. Patent No. 5,770,442), Liessner (Gene Therapy, 2001, 8: 49-57), and Legrand (WO 98/44121). Therefore, Applicant submits that all claims share a special technical feature. Additionally, Applicant argues that the inventions of Groups I-IV are closely related and would not require separate searches. This is not found persuasive because the prior art teaches a modified adenoviral fiber comprising at least one mutation located at positions 506, 508, and/or 555 of the wild type Ad5 fiber protein set forth by SEQ ID NO: 1 (see Wickham et al., U.S. Patent No. 6,455,314; column 7, lines 10-18, column 17, lines 20-27, Table 1). Additionally, Applicant's argument that the inventions of Groups I, III, and IV do not necessitate separate searches is not found persuasive because the each invention encompasses different embodiments that require distinct searches in the patent and non-patent literature. For example, the invention of Group I is drawn to a series of specific substitutions not specifically disclosed by the inventions of Groups III and IV; a

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search in the patent and non-patent literature for the elected invention (i.e., Group III) did not render results regarding these substitutions (i.e., they require additional searches and considerations). Similarly, the search for the invention of Group I did not render results relevant for the invention of Group IV. For the reasons above, a search and examination of these inventions together would be a burden for the Examiner. However, since the search for the invention of Group III rendered results relevant for the invention of Group II (claim 19), the invention of Group II is hereby rejoined and presently examined:

The restriction requirement between the inventions of Groups I, III, and IV is still deemed proper and is therefore made FINAL.

Claims 5 and 6 have been cancelled. Claims 2-4, 7-15, 17, 18, 28, 35-39, 42, and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim.

Claim 1 has been amended.

Claims 1, 16, 19-34, 40, and 41 are under examination.

Note: Change in Art Unit and SPE

The Examiner of record is now Ileana Popa, Art Unit 1633. Therefore, future correspondence should reflect such changes. Also, at the end of the Action is the information regarding the SPE and the Art Unit.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 16, 19-27, 30-34, 40, and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Wickham et al. (U.S. Patent No. 6,455,314).

Wickham et al. teach (i) a mutated adenoviral fiber protein, wherein the adenoviral fiber protein comprises at least one mutation affecting the lysine at position 506, the histidine at position 508, and the serine at position 555 of the wild type adenoviral fiber protein set forth by SEQ ID NO: 1, and wherein the affected amino acid residues are involved in the interaction with cellular receptors containing glycosaminoglycans or sialic acid (claim 1), (ii) a trimer comprising the mutated adenoviral fiber protein (claim 16), (iii) a DNA encoding the mutated adenoviral fiber protein (claim 19), and (iv) an adenoviral particle wherein wild type adenoviral fiber is replaced with the mutated adenoviral fiber protein, wherein the adenoviral particle comprises a penton base having mutations affecting a native RGD sequence (claim 21), wherein the adenoviral particle exhibits reduced ability to interact with the native receptors, wherein the adenoviral particle can further include non-native ligands that can bind cellular receptors and wherein the non-native ligands can be incorporated into

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the fiber at any location that exposes the ligand, such as the terminus of the fiber protein (i.e., genetically coupled to a viral polypeptide exposes at the surface, wherein one of the locations could be the C-terminus) (claims 20 and 22-27) (Abstract, column 7, lines 10-18 and 37-67, column 9, lines 20-67, column 10, lines 1-67, column 12, lines 29-31, column 17, lines 20-27, Table 1; see also the attached sequence alignment).

Wickham et al. teach that the adenoviral particle can comprise adenoviral genome and it can be replication defective (claims 30 and 31), that the adenoviral particle can be used deliver genes to target cells, i.e., the genes are operably linked to tissue-specific promoters for their expression into the host cell, wherein the host cell have surface receptors capable of binding the ligand exposed on the surface of the adenoviral particle (claims 32-34) (column 13, lines 7-67, column 14, lines 25-30). Wickham et al. also teach a composition comprising the adenoviral particle and a pharmaceutically acceptable carrier (claim 40), wherein the adenoviral particle is conjugated to lipid derivatives of PEG (claim 41) (column 1, lines 42-50, column 14 bridging column 15).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 1, 16, 19-27, 29-34, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wickham et al., in view of Seth et al. (U.S. Patent No 5,928,944).

The teachings of Wickham et al. are applied as above for claims 1, 16, 19-27, 30-34, 40, and 41. Wickham et al. do not teach the adenoviral particle being an empty capsid (claim 29). Seth et al. teach a method of adenoviral-mediated transfection, wherein the adenovirus is an empty capsid (Abstract, column 5, lines 22-35, column 8, lines 54-58). It would have been obvious to one of skill in the art, at the time the invention was made, to obtain an empty adenovial capsid comprising the mutated fiber protein of Wickham et al., with a reasonable expectation of success. One of skill in the art would have been motivated to obtain such capsids to use them according to the teachings of Seth et al., who disclose that such capsids are efficient in mediating transfection without destroying the host cell (column 8, lines 24-58). One of skill in the art would have been expected to have a reasonable expectation of success in making empty capsid because the art teaches that such capsids can be successfully obtained. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

6. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

Joe Woitach
AU 1633